

REMARKS

In the Office Action, Claims 1-21 are rejected under 35 U.S.C. §112, second paragraph; and Claims 1-24 are rejected under 35 U.S.C. §103. Claims 1, 7, 13 and 19 have been amended. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made." Applicants respectfully submit that the rejections have been overcome or are improper in view of the amendments and for the reasons set forth below.

In the Office Action, Claims 1, 7, 13 and 19 are rejected under 35 U.S.C. §112, second paragraph. At the outset, the Patent Office asserts that the claim term "and being in the form of" is vague and indefinite. In response, Applicants have amended Claims 1, 7, 13 and 19 to include the claim term ", the dietary protein hydrolysates including" in place of the claim term at issue. Applicants note for the record that the amendment was made for clarification purposes and was not intended to narrow the scope of the claimed subject matter.

Further, the Patent Office asserts that the claim terms "in the form of a mixture of different size peptides and free amino acids," "intact proteins comprising bioactive proteins," "intact proteins that are at least partially in the form of bioactive peptides" and "intact proteins are at least partly in the form of bioactive peptides" are ambiguous in meaning. Applicants believe that the scope and meaning of these claim terms are clearly defined.

For example, the Specification discloses that the dietary protein hydrolysates can include di- and tri-peptides at greater than 25% by weight which can increase the rate of protein synthesis in the jejunum and the duodenum. See, Specification, page 4, lines 25-29. The dietary protein hydrolysates of the claimed invention may also include free amino acids. See, Specification, page 5, lines 2-7. Thus, Applicants believe that one skilled in the art viewing same would clearly understand the scope and meaning of the claim term "a mixture of different size peptides and free amino acids."

With respect to the claim terms "intact proteins comprising bioactive proteins," "intact proteins that are at least partially in the form of bioactive peptides," and "intact proteins that are at least partly in the form of bioactive peptides," the Specification discloses that intact proteins may be individual or enriched animal or vegetable protein fractions that include, for example, whole milk, caseins, whey proteins, soy proteins or rice proteins. Further, the intact protein fraction may contain bioactive peptides, such as TGF- β 2 or a source of bioactive peptides, such

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as beta-casein liberated in the gut by enzymatic hydrolysis. See, Specification, page 2, lines 18-26. Thus, Applicants believe that the Specification is clearly sufficient in detail to apprise one skilled in the art of the scope and meaning of the claim terms at issue.

Accordingly, Applicants respectfully request that the rejection of Claims 1, 7, 13 and 19 under 35 U.S.C. §112 be withdrawn.

In the Office Action, Claims 1-24 are rejected under 35 U.S.C. §103 in view of U.S. Patent No. 4,977,137 ("*Nichols*"). Applicants believe that this rejection is improper.

Of the pending claims, Claims 1, 7, 13 and 19 are the sole independent claims. Claim 1 relates to a nutritional enteral composition intended for favoring the growth and maturation of non-mature gastro-intestinal tracts of young mammals; Claim 7 relates to a method of preparing a nutritional enteral composition intended for favoring the growth and maturation of non-mature gastro-intestinal tracts of young mammals; Claim 13 relates to a method for providing nutrition to young mammals having non-mature gastrointestinal tracts; and Claim 19 relates to a method of promoting the growth and maturation of non-mature gastrointestinal tracts of young mammals. Each of the independent claims recites a nutritional composition that includes a mixture of dietary protein hydrolysates and intact proteins. The dietary hydrolysates have a degree of hydrolysis that ranges from about 10% to less than 50% by weight and include a mixture of peptides and free amino acids wherein the free amino acids are present in an amount of up to about 20%. The intact proteins includes, at least in part, bioactive peptides.

The nutritional compositions of the claimed invention provide for very high nutrient needs for growth and development of non- or pre-mature gastro-intestinal tracts of young mammals. Further, the nutritional compositions of the claimed invention can ensure optimal digestion and utilization (for tissue accretion) of the protein source and intends to minimize the nitrogen waste of the organism. Moreover, the protein mixture of the claimed invention can provide a better source of amino acids to meet the general amino acid needs of the patient in addition to specifically favor maturation of individual organs. See, Specification, page 3, lines 4-10.

In contrast, Applicants believe that the cited art fails to disclose or suggest a number of features of the claimed invention. For example, the primary focus of the *Nichols* reference relates to a single dietary ingredient, namely milk lactoferrin. See, *Nichols*, Abstract. The milk lactoferrin purportedly can be added to or supplement a variety of different commercially-

available infant formulas to stimulate gastrointestinal growth. See, *Nichols*, cols. 6-8. Clearly, this clearly suggests that *Nichols* considers milk lactoferrin to be "a sole growth promoter sufficient to promote gastrointestinal tract growth in human infants and infant animals." See, *Nichols*, Claim 1.

This clearly contrasts the claimed invention that relates to nutritional compositions with a protein source that combines intact proteins and dietary protein hydrolysates to promote growth and maturation of non-mature gastrointestinal tracts of young animals. Indeed, *Nichols* fails to disclose the specific ranges and ratios of the ingredients of the nutritional composition as required by the claimed invention as even admitted by the Patent Office. Therefore, Applicants do not believe that one skilled in the art viewing *Nichols* would be inclined to modify same to arrive at the claimed invention contrary to the Patent Office's position.

Based on at least these differences between the claimed invention and the cited art, Applicants believe that the cited art fails to disclose or suggest a number of features of the claimed invention. Therefore, Applicants respectfully submit that *Nichols* fails to render obvious the claimed invention.


Accordingly, Applicants respectfully request that the obviousness rejection be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

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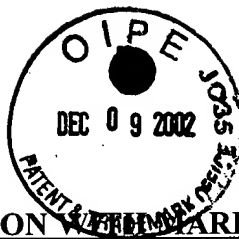

Thomas C. Basso

Reg. No. 46,541

P.O. Box 1135

Chicago, Illinois 60690-1135

Phone: (312) 807-4310



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

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In the Claims:

Claims 1, 7, 13 and 19 have been amended as follows:

1. (Twice Amended) A nutritional enteral composition intended for favoring the growth and maturation of non-mature gastro-intestinal tracts of young mammals comprising:

a mixture of dietary protein hydrolysates having a degree of hydrolysis in a range of from about 10% to less than 50% by weight, the dietary protein hydrolysates including ~~and being in the form of~~ a mixture of different size peptides and free amino acids, the free amino acids being present in an amount of up to about 20% (each calculated as nitrogen x 6.25); and

intact proteins comprising bioactive peptides.

7. (Twice Amended) A method of preparing a nutritional enteral composition intended for favoring the growth and maturation of non-mature gastro-intestinal tracts of young mammals comprising the step of using as a protein source a mixture of dietary protein hydrolysates having a degree of hydrolysis in a range of from about 10% to less than 50% by weight, the dietary protein hydrolysates including ~~and being in the form of~~ a mixture of different size peptides and free amino acids, the free amino acids being present in an amount of up to about 20% (each calculated as nitrogen x 6.25) and intact proteins that are at least partially in the form of bioactive peptides.

13. (Amended) A method for providing nutrition to young mammals having non-mature gastrointestinal tracts, comprising the step of administering a composition which contains as a protein source a mixture of dietary protein hydrolysates having a degree of hydrolysis in a range of from about 10% to less than 50% by weight, the dietary protein hydrolysates including ~~and being in the form of~~ a mixture of different size peptides and free amino acids, the free amino acids being present in an amount of up to about 20% (each calculated as nitrogen x 6.25) and intact proteins that are at least partly in the form of bioactive peptides.

19. (Amended) A method for promoting the growth and maturation of non-mature gastrointestinal tracts of young mammals, comprising the steps of administering a composition

which contains as a protein source a mixture of dietary protein hydrolysates having a degree of hydrolysis in a range of from about 10% to less than 50% by weight, the dietary protein hydrolysates including ~~and being in the form of a~~ mixture of different size peptides and free amino acids, the free amino acids being present in an amount of up to about 20% (each calculated as nitrogen x 6.25) and intact proteins that are at least partly in the form of bioactive peptides.